K021341

AUG 01 2002

510 (k) Summary

510 (k) Number:
~~K990140~~

Device Name:
Normed Bone Transport Distraction Device

Device Identification:
External Mandibular Fixator and/or Distractor

Regulatory Class:
II

Product Code:
Product Code: JEY

Introduction of Normed Bone Transport Distraction Device,
510 (k) number K990140, by an additional distributor, Osteomedics®, Inc.

The Normed Bone Transport Distraction Device is authorized by Food and Drug Administration under the 510 (k) number K990140 to be distributed in the United States of America by Ace Surgical Supply Company, Incorporated [1]. Osteomedics® Inc. is intended to be an additional distributor of the same device through out United States of America. The device intended to be introduced by Osteomedics® Inc., is the same identical product described in the 510 (k) number K990140. The manufacturer, product design, product material, manufacturing process, device description, product intend use, labeling[2], quality assurance procedures, sterilization, substantial equivalency information and operational principal is identical to the information available in the 510 (k) number K990140

Official Contact Person:
Albert Enayati
President
Osteomedics® Inc.
809 Carter Lane
Paramus, NJ 07652
Tel: (201) 444-7306
Fax: (201) 444-7395
E-mail: osteomedics@aol.com

[1] Ace Surgical Supply Company, Incorporated, 1034 Pearl Street, P.O. Box 1710 Brockton , Massachusetts 02408

[2] Labeling will include Osteomedics® Inc. information.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 01 2002

Mr. Albert Enayati
President
Osteomedics, Incorporated
809 Carter Lane
Paramus, New Jersey 07652

Re: K021341
Trade/Device Name: Normed Bone Transport Distraction Device
Regulation Number: 872.4760
Regulation Name: Bone Plate
Regulatory Class: II
Product Code: JEY
Dated: July 23, 2002
Received: July 25, 2002

Dear Mr. Enayati:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K021341

Indications for use

510 (k) Number (if known): K990140

Device Name: Normed Bone Transport Distraction Device

Indications for use:
The intended use of the Normed Transport Distraction Device is described and is identical to the 510 (k) number K990140 in which, the Normed Transport Distraction Device is designed for use in totally or partially edentulous mandibles or maxillae to increase bone height and mass by means of distraction osteogenesis. As clinically defined the gradual step lengthening of a callus for distraction osteogenesis can be achieved with the transitory use of the Normed Transport Distraction Device. This Normed transitory monofocal or bifocal distraction device is indicated for use in maxillofacial alveolar and small craniofacial skeletal bones. Clinical indications are as follows:

- Tumor Resections
- Severe trauma which make continuous bone segments no longer possible
- Bone grafting defects
- Sever open mandibular fractures
- Facial deformity corrections

Contraindications:
The Normed Transport Distraction Device is contraindicated in patients with insufficient available bone, poor bone quality and generalized diseases, allergies or habits (uncontrolled diabetes, blood dycrasias, hyperthyroidism, AIDS, alcohol addictions, psychiatric disorders, oral infections, malignancies, myocardial infection within the last 12 months, heavy smoking, use of chewing tobacco, poor oral-hygiene, etc.) that may contribute to poor healing or osteogenesis formation of bone. The patient's good medical health status and history is mandatory. In addition, a radiographic evaluation to examine the anatomical condition of the patient for proper use of the device to the defined surgical protocol is required.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)

Prescription use ✓ OR OVER – THE – COUNTER USE _____

(Per 21 CFR 801.109) (Optional Format 1-2-96)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K021341